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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,158	12/30/1999	Thomas J. Gardella	0609.4780001	6018
26111	7590	06/17/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/475,158

Applicant(s)

GARDELLA ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05/20/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-11,14 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5-8,10,11,14 and 44-46 is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### **Amendments, and/or Claims Status of Application**

Upon further consideration, the finality of the rejection of the last Office action is withdrawn.

Applicants' amendments filed on 05/20/2005 and 02/11/2005 have been entered in full. Claims 1, 5-11, 14, and 44-46 are pending and are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Withdrawn Rejections and/or Objections**

The rejection of claims 1, 2, 4-6, 10, 11, 37, 41-43, and 46 under 35 U. S. C. §112, 1<sup>st</sup> paragraph for scope of enablement, as set forth in the previous office actions (Paper No. 04032004, mailed on 05/04/2004; Paper No. 11182004, mailed on 11/22/2004), has been withdrawn in view of amended and canceled claims.

The rejection of claims 1, 2, 5, 6, 37, 41-43, and 46 under 35 U.S.C. §112, second paragraph, as set forth in the previous office actions (Paper No. 04032004, mailed on

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05/04/2004; Paper No. 11182004, mailed on 11/22/2004), has been withdrawn in view of amended and canceled claims.

The objection to claim 2 as being of improper dependent form for failing to further limit the subject matter of a previous claim has been made moot by Applicants' cancellation of the claim.

**Claim Rejections Under 35 U. S. C. §112, 1<sup>st</sup> Paragraph (Scope of Enablement)**

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides of claims 1, 5-8, 10, 11, 14, and 44-46, does not reasonably provide enablement for the polypeptides of SEQ ID NO: 3, 5, and 6 wherein there is a single amino acid substitution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claim.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

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Claim 9 is drawn to an isolated polypeptide of SEQ ID NOS: 3, 5, or 6 wherein there is a single amino acid substitution. The claim does not require that the polypeptide possess a particular biological function. Thus, the claim is broad and encompasses a genus of variants or homologues of the polypeptides of SEQ ID NOS: 3, 5, and 6. The present invention is related to polypeptides of the formula S-(L)<sub>n</sub>-B, wherein S is an amino-terminal signaling functional domain of PTH, L is a linker molecule present n times, whereas B is a carboxy terminal binding domain of PTH (1-340 or PTHrP (1-34). Since the claim does not define where an amino acid in SEQ ID NO: 3, 5, and 6 is substituted and what type of amino acid is substituted with, the single amino acid substitution can occur in any parts of the polypeptide: the signaling domain, the binding domain, or the linker. Moreover, any amino acid can be used to substitute a single amino acid of SEQ ID NO: 3, 5, and 6, regardless of its form (R or L), size, hydrophobic or hydrophilic.

While providing sufficient guidance and/or working examples on how to make and/or use the polypeptides of claims 1, 5-8, 10, 11, 14, and 44-46, the instant disclosure fails to provide sufficient guidance and/or working examples to make and use such a broad of genus of polypeptides of SEQ ID NO: 3, 5, and 6 wherein a single amino acid is substituted. In view of the instant disclosure, an artisan would expect a polypeptide of the formula S-(L)<sub>n</sub>-B to stimulates intracellular accumulation of cyclic cAMP if the linker is (Gly)<sub>n</sub>, n=5-10. However, it is unpredictable whether a polypeptide with a substituted linker (e.g., Gly in the linker is substituted with a highly hydrophilic amino acid, Arginine, or with an amino acid with a aromatic chain, tryptophan) would retain the same

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functional activity, since neither the instant disclosure nor the prior art provide sufficient directions guiding an artisan to make and use the a compound comprising such an undefined linker. In this regard, it is noted that, while PG5 shows an induction of cAMP in COS-7 cells expressing human PTH-1receptor, PG9, which has 4 more glycine residues in the linker, has a minimal effect on induction of cAMP (Fig. 3).

Accordingly, in view of the breadth of the claims, the complexity of the nature of the invention, unpredictability of the work related to the present invention, lack of sufficient guidance and working examples, one skilled in the art would not be able to make and use the claimed invention commensurate in scope with the claims without undue experimentation.

### **Conclusion**

Claims 1, 5-8, 10, 11, 14, and 44-46 are allowed.

### **Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.

Examiner

June 15, 2005